MAR 0 3 2014

510(K) SUMMARY

Sponsor Information:

Name of 510(k) sponsor:	GlycoBioSciences, Inc.
Address:	7 Timber Court Georgetown, Ontario L7G 4S4 Canada
Contact information:	Kevin Drizen President GlycoBioSciences, Inc. 7 Timber Court Georgetown, Ontario L7G 4S4 Canada Phone: 905-854-0631 Fax: 905-702-1709 kdrizen@glycobiosciences.com

Device Information:

Proprietary name of device: IPM Wound Gel Bio

Generic/classification name: Dressing, Wound and Burn, Hydrogel W/Drug and/or Biologic

Product code (classification): Product Code MGQ; Unclassified

Legally Marketed Predicate Devices:

Bionect® Hydrogel (K984413)
L.A.M. IPM Wound Gel (K020325)- L.A.M. IPM Wound Gel (K020325); April 15, 2002

Device Description:

IPM Wound Gel Bio is a clear viscous, odorless, aqueous gel, composed principally of sodium hyaluronate, a derivative salt of Hyaluronic acid. The proportion of sodium hyaluronate "w/w" in the formulation is 2.5%.

Hyaluronic acid is a molecule which is normally found in various parts of the body. Hyaluronic acid is an extracellular matrix component of human skin. The Hyaluronic acid used in IPM Wound Gel Bio is derived from a synthetic source, more specifically from a bacterial fermentation process. IPM Wound Gel Bio serves to maintain a moist wound environment. The maintenance of a moist wound environment is widely recognized to positively contribute to wound healing process.

Other ingredients in IPM Wound Gel Bio are as follows:
hydroxyethyl cellulose (1%), methylparaben (0.2%), as well as polyethylene glycol (3%) and purified water, USP (approx. 93%).

IPM Wound Gel Bio is presented in carton boxes with 4 laminated tubes of 10g (0.35oz).

IPM Wound Gel Bio has similar specifications of L.A.M. IPM Wound Gel, with exception to its source of Hyaluronic acid.

Intended Use:

IPM Wound Gel Bio serves to maintain a moist wound environment. The maintenance of a moist wound environment is widely recognized to positively contribute to wound healing process. IPM Wound Gel Bio also helps to relieve dry waxy skin irritations associated with dry skin conditions.

Indications for Use:

"OTC":

L.A.M. IPM Wound Gel/IPM Derm Gel is indicated for management of minor burns (1st degree burns), minor abrasions, minor cuts and helps to relieve dry waxy skin irritations associated with dry skin conditions.

Rx:
Under the supervision of a health care professional;

• IPM Wound Gel Bio is indicated for management of exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative incisions and donor sites), mechanically or surgically debrided wounds, and for second degree burns.

Device Technological Characteristics:

IPM Wound Gel Bio is a clear viscous, odorless, aqueous gel. Hyaluronic acid is an extracellular matrix component of human skin. The Hyaluronic acid used in IPM Wound Gel Bio is derived from a synthetic source, more specifically from a bacterial fermentation process. IPM Wound Gel Bio serves to maintain a moist wound environment. The maintenance of a moist wound environment is widely recognized to positively contribute to wound healing process.

Products for topical use have their safety established through biocompatibility tests. The biocompatibility test performed for L.A.M. IPM Wound Gel, included reports of Cytotoxicity Study, Modified ISO Accute Reactivity in Rabbits, ISO Accute Systemic Toxicity in Mouse, In Vitro Hemolysis and ISO Sensitization. All of them meet the requirements of the ISO 10993 and USP <10317> and resulted under the anticipated specifications. The Histological Study in Porcine is another study that demonstrated the effectiveness of L.A.M. IPM Wound Gel on partial thickness wound healing in porcine.

Bio fermented HA passed biocompatibility evaluations and thus demonstrated substantial equivalence to the predicate device in this respect, i.e., biocompatibility.

Comparison with Predicate Device:

IPM Wound Gel Bio is similar in technological characteristics and indications to the predicates.

Name of Device	L.A.M. IPM™ Wound Gel (K020325)	Bionect® Hydrogel (Jaloplast™) (K984413)	IPM™ Wound Gel Bio (K123193)
Classification Name	Dressing, Wound And Burn, Hydrogel W/Drug And/Or Biologic	Dressing, Wound And Burn, Hydrogel W/Drug And/Or Biologic	Dressing, Wound And Burn, Hydrogel W/Drug And/Or Biologic
Intended Use	Provides a moist wound environment that is supportive to wound healing	Provides a moist wound environment that is supportive to wound healing	Serves to maintain a moist wound environment. The maintenance of a moist wound environment is widely recognized to positively contribute to wound healing process. IPM Wound Gel Bio also helps to relieve dry waxy skin irritations associated with dry skin conditions.
Indications for Use	Over the counter: L.A.M. IPM Wound Gel is indicated for the management of minor burns (1st degree burns), minor abrasions and minor cuts. Under the supervision of a healthcare professional: L.A.M. IPM Wound Gel is indicated for the management of exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative incisions and donor sites), mechanically or surgically debrided wounds, and 2nd degree burns"	Over the counter: Bionect is indicated for the management of minor burns (1st degree burns), minor abrasions and minor cuts, minor irritations of the skin Under the supervision of a healthcare professional: Bionect is indicated for the management of exudating wounds such as leg ulcers, pressure ulcers,diabetic ulcers, surgical wounds (post-operative incisions and donor sites), mechanically or surgically debrided wounds, and 2nd degree burns"	OTC: IPM Wound Gel Bio is indicated for management of minor burns (1st degree burns), minor abrasions, minor cuts and helps to relieve dry waxy skin irritations associated with dry skin conditions. Rx: Under the supervision of a health care professional; • IPM Wound Gel Bio is indicated for management of exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (postoperative incisions and donor sites), mechanically or surgically debrided wounds, and for second degree burns.
Device Description	Aqueous gel composed principally of sodium hyaluronate	Aqueous gel prepared from hyaluronate and purified water	Aqueous gel composed principally of sodium hyaluronate
Hyaluronate Source	Avian	Unknown	Bacterial fermentation
Shelf Life	24 months	24 months	24 months

Considering that the only difference is the source of HA and that proposed indications are similar to already approved to the predicates indicated by Glyco, it is fair to understand that quality, safety and effectiveness are demonstrated and are comparable to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 3, 2014

GlycoBioSciences Incorporated
Mr. Kevin Drizen
President
7 Timber Court
Georgetown, Ontario L7G 4S4
CANADA

Re: K123193
Trade/Device Name: IPM Wound Gel Bio
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 10, 2014
Received: January 13, 2014

Dear Mr. Drizen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K123193

Device Name
IPM Wound Gel Bio

Indications for Use (Describe)
"OTC":
IPM Wound Gel Bio is indicated for management of minor burns (1st degree burns), minor abrasions, minor cuts and helps to relieve dry waxy skin irritations associated with dry skin conditions.

Rx:
Under the supervision of a health care professional:

- IPM Wound Gel Bio is indicated for management of exudating wounds such as leg ulcers, pressure ulcers, diabetic ulcers, surgical wounds (post-operative incisions and donor sites), mechanically or surgically debrided wounds, and for second degree burns.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S